

MEMORANDUM

SDMS Document ID

2007172

To:

Bonnie Lavelle

Cc:

Project File

From:

John Guttmann, SRC

Date:

February 25, 2003

RE:

VBI70 Health Study QA/QC Summary

1.0 INTRODUCTION

The Colorado Department of Public Health and Environment (CDPHE) and the University of Colorado Health Sciences Center (UCHSC) conducted a study in 2002 to gain information on current levels of childhood exposure to lead and arsenic at the VBI70 Superfund site, and to investigate how those levels correlate with soil concentration values and with various behavioral and demographic traits. Exposure to arsenic was assessed by measuring total non-dietary arsenic in urine and total arsenic in hair, and exposure to lead was evaluated by measuring blood lead concentrations. Study subjects were children ages \leq 83 months.

USEPA Region 8 supported this study by providing analytical services for arsenic and lead in biological samples. The details of the sample handing and analysis plan and the Standard Operating Procedures for the project are provided in the Quality Assurance Project Plan (QAPP) developed for this effort (USEPA 2002).

USEPA assigned the task of arranging for sample analysis to Syracuse Research Corporation (SRC). As part of the analysis support, SRC collected a number of types of quality assurance (QA) samples and performed QA assessments throughout the study to help ensure the quality and reliability of the data could be evaluated with respect to the goals established in the QAPP (USEPA 2002). This memo summarizes the QA steps that were performed and tracked, and presents the resulting QA data that may be used to assess data reliability.

2.0 URINARY ARSENIC QA/QC RESULTS SUMMARY

2.1 Laboratory Control Samples

Arsenic in urine was analyzed by National Medical Services (NMS) in Willow Grove, PA. Samples were submitted weekly, usually in lots of 100-200. Each weekly shipment was considered a sample Delivery Group (SDG).

NMS analyzed two types of laboratory control samples (LCSs) with each SDG: BioRad® and Centre de Toxicologie du Quebec (CTQ) S-class samples. The BioRad® samples consisted of certified low and high arsenic levels. The CTQ S-class samples consisted of certified levels of arsenate (As+5), monomethyl arsonic acid (MMA), and total arsenic in urine from workers and/or in seafood.

The results for these LCS samples are shown in Figure 1. As seen in Panels A-D, all (53 out of 53) of all CTQ S-class LCS were within established acceptance criteria. As shown in Panels E and F, out of a total of 252 BioRad® samples, all but five (98.0%) fell within the established acceptance criteria. Combining both data sets, the overall rate of acceptable LCS samples is 300/305 = 98.4%.

2.2 PE Samples

Performance evaluation (PE) samples are samples of known concentration that are submitted to the laboratory in a random and blind fashion. At the beginning of the study, PE samples were prepared by adding known amounts of various forms of arsenic to control human urine. These samples were prepared by Dr. Stan Casteel at the University of Missouri, and are referred to in this memo as Casteel PE samples. The samples prepared by Dr. Casteel are listed below, along with the measured concentration (total arsenic) in each sample:

Arsenic Species Added	Target Increment (ug/L)	Measured Value (ug/L) (a)
None	0.0	4.43
Arsenite (As+3)	5	9.63
	15	20.7
Arsenate (As ⁻⁵)	5	10.5
	15	20.0

Monomethyl arsonic acid (MMA)	5	7.4
	15	14.7
Dimethyl arsinic acid (DMA)	5	8.6
	15	17.0
Arsenobetaine	20	24.7

⁽a) Value is mean of triplicate measurements of total arsenic.

In general, each SDG contained one (or sometimes two) samples of each type of Casteel PE sample. The nominal value of each inorganic or methyl arsenic PE sample was defined as:

Nominal = Measured Concentration (total) - Blank(total) + Blank(total inorganic)

This adjustment is needed because the measured value is based on total arsenic, while the analytical results are based on total inorganic arsenic. Acceptance criteria established in the QAPP for inorganic and methyl arsenic forms was a relative percent difference (RPD) of no more than \pm 20% of the nominal value. For arsenobetaine (which should not be recovered in the analytical procedure), the nominal value is equal to the blank urine (assuming zero percent recovery of arsenobetaine), and the acceptance criterion is the blank value plus 10% of the spiked arsenobetaine concentration (1.1+2.0 = 3.1 ug/L).

	Spiked Value (ug/L)	Nominal Value (ug/L)	Acceptance Criteria (ug/L)	
Arsenic Species Added			Lower	Upper
None	0.0	1.1	0	2
Arsenite (As+3)	5	6.3	5.0	7.6
	15	17.3	13.9	17.3
Arsenate (As ⁺⁵⁾	5	7.2	5.7	7.2
	15	16.7	13.3	16.7
Monomethyl arsonic acid	5	4.1	3.3	4.1
(MMA)	15	11.3	9.1	11.3
Dimethyl arsinic acid (DMA)	5	5.2	4.2	5.2
	15	13.7	10.9	13.7
Arsenobetaine	20	1.1 (b)	0	3.1

Results are shown in Figure 2. As seen in Panel A, the average level of total inorganic arsenic in the blank (unspiked) urine sample was about 1.1 ug/L, and this held relatively constant over time. Recovery of arsenobetaine (Panel B) was very low in all SDGs, as intended. Recovery of inorganic arsenic (Panel C and Panel D) was within acceptance criteria for nearly all samples from SDGs 1-5, but began to exhibit anomalous results (a mixture of lower and higher than expected recoveries) in SDGs 6-9. Similarly, recovery of MMA (Panel E) was within acceptance criteria for SGDs 1-5, but anomalous results began to occur in SDGs 6-9. Recovery of DMA (Panel F) was consistent but lower than expected in SDGs 1-5, and then it too began to display substantial variability in SDGs 6-9.

Because of the increased variability observed in the Casteel PE samples beginning in SDG6, all field samples from SDG 6 were re-analyzed to ensure that the results were reliable. A correlation comparison between the initial and repeat results for the samples in this SDG yielded a Pearson coefficient (R²) of 0.920, indicating good agreement between the two analyses. This suggested that the unexpected results for the PE samples might be associated with a deterioration of the PE samples themselves rather than a deterioration of analytical quality. One potential cause was the growth of mold in the PE samples that laboratory personnel observed to occur in some of the samples after about week 5.

Consequently, SRC arranged for the preparation of a second set of PE samples. These were prepared by addition of various forms of arsenic to water rather than to control human urine. This was done to avoid any future problems attributable to mold growth in urine. The second set of PE samples were prepared by Environmental Resource Associates (ERA) in Denver CO. These are referred to in this memo as ERA PE samples. The list of ERA PE sample types and concentration levels is the same as for the Casteel PE samples (see above).

Acceptance criteria for these samples were the same as for the Casteel PE samples (RPD $\pm 20\%$), except that nominal values were based on the spiked levels. Results are shown in Figure 3.

Results for the control sample (Panel A) were all less than the detection limit (1 ug/L). As before, recovery of arsenobetaine was very low (Panel B), as intended. Recoveries of arsenite (Panel C), arsenate (Panel D), and MMA (Panel E) were all generally within acceptance criteria, while recovery of DMA (Panel (F) tended to be slightly lower than acceptance criteria.

2.3 Blind Split Samples

Blind split samples were prepared by submitting two equal aliquots of the same sample to the laboratory

using two different sample numbers. These were submitted at a rate of about 5%. The acceptance criterion for field split samples established in the QAPP was an RPD of no more than 30%. The results are shown in Figure 4.

Nearly all split samples from all SDGs were within acceptable bounds except for split samples from SDG 9. In this group, four out of four split samples had RPDs greater than 30%. To investigate the basis of this unexpected outcome, SRC resubmitted 11field samples from SDG 9 plus blind splits of these same 11field samples (a total of 22 samples). Figure 5 (upper panel) compares the results of the re-analyses (two values per sample) to the original values obtained for SDG 9. As seen, there is moderately good agreement between some pairs of analyses, but poor agreement for other pairs. The lower panel shows the agreement between the two blind splits in the re-analyses. As seen, agreement is good.

These results indicate that results for some samples in SDG 9 may have lower confidence than for other samples from within the study. The reason for the relatively poor performance on split samples and some repeat analyses in SDG 9 is not known.

3.0 BLOOD LEAD QA/QC RESULTS SUMMARY

Laboratory Control Samples

All blood samples were analyzed for lead by Tamarac Medical, Inc., in Denver, CO. As part of their internal QA program, Tamarac analyzed at least two LCS samples (generally one "low" and one "high") for each set of 10 field samples. These LCS samples (a total of 10 different types) were obtained from a variety of different commercial sources. In the event that an LCS sample fell outside the recommended acceptance criteria for that LCS (typically \pm 4 ug/dL), Tamarac re-calibrated the instrument and analyzed another LCS. In the event of two successive LCS samples outside acceptance criteria, Tamarac immediately stopped all analysis operations and investigated the problem.

The results are shown in Figure 6. As seen, out of a total of 534 LCS samples analyzed over the course of 26 SDGs, 526 (98.5%) were within acceptance criteria and 8 (1.5%) were outside acceptance criteria. Note that the decrease in values that occurred near the end of the study was associated with a change in the identity (and nominal level) of the LCS samples rather than a decrease in blood lead recovery.

PE Samples

SRC obtained four different samples of blood from the Centers for Disease Control and Prevention (CDC) for use as blind PE samples. Consensus (nominal) concentrations of lead in these samples were determined by CDC using GFAAS or ICP-MS. A summary of these samples is listed below:

CDC Sample ID	Nominal Value (ug/dL)
194	0.4
1494	4.5
994	8.9
396	14.8

With the exception of SDG 1, in which two of each CDC PE sample (n=8) were analyzed, one of each CDC PE sample was included in each SDG (n=4). In accord with recommendations from CDC, the acceptance criterion for each of these PE samples was ± 4 ug/dL.

The results are shown in Figure 7. As seen, out of 113 CDC PE samples, 111 (98%) were within acceptance criteria, with only 2 falling slightly outside of the acceptance criteria.

Duplicate Samples

A duplicate sample of blood was collected from children participants whenever the opportunity arose (i.e., a good flow of blood and the parents and child agreed). A total of 106 such samples were obtained and submitted to the laboratory in a blind and random fashion.

Figure 8 compares the results of the initial and the duplicate values for these 106 children. As seen, there was generally good agreement between the blood lead estimates for the original and duplicate samples. The average absolute difference between first and second samples was 0.9 ug/dL, with an overall correlation coefficient between original and duplicate samples of 0.876.

4.0 HAIR ARSENIC QA/QC RESULTS SUMMARY

All hair samples were analyzed for arsenic by the Centre de Toxicologie du Quebec (CTQ), in Quebec, Canada. As part of their internal QA program, CTQ analyzed one LCS (provided by Shanghai Institute of Nuclear Research, China) per ten field samples. The results are shown in Figure 9. As seen, all LCS

results fell within the acceptance criteria recommended by the supplier.

5.0 FIELD AUDITS

In addition to providing QA on the analytical portion of this project, SRC also provided oversight for some field activities to help ensure samples were being collected and handled in accord with the project plan (USEPA 2002). A total of 8 eight field audits were performed, in which field activities were observed by SRC employees who were familiar with the project plan. Following each audit, a memo was submitted to both USEPA and the UCHSC project team. These memos (attached as Appendix A) summarized observations and recommendations (as necessary) for improving sample collection and documentation procedures. In general, the field activities were conducted in accordance with the protocols outlined in the project plans and procedures taught during training sessions. No significant concerns were identified during SRC's oversight of field activities.

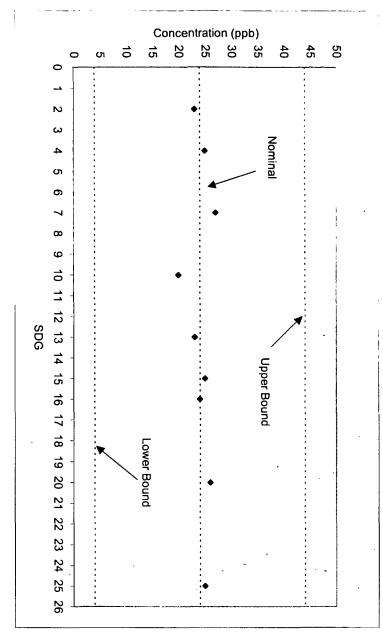
6.0 REFERENCES

USEPA. 2002. Sample Analysis and Quality Assurance Plan for Urinary Arsenic and Blood Lead among Residents of VBI70 Neighborhoods. Prepared by USEPA Region 8 with technical assistance from Syracuse Research Corporation. June 2002

FIGURES

FIGURE 1. NMS RESULTS FOR URINARY ARSENIC LCS

Panel A: LCS = CTQ MMA





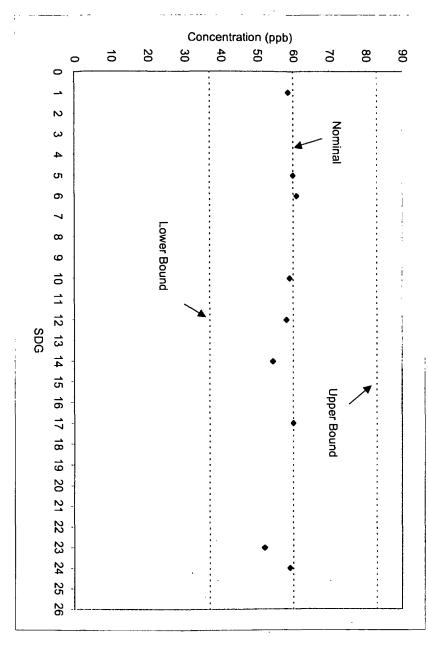
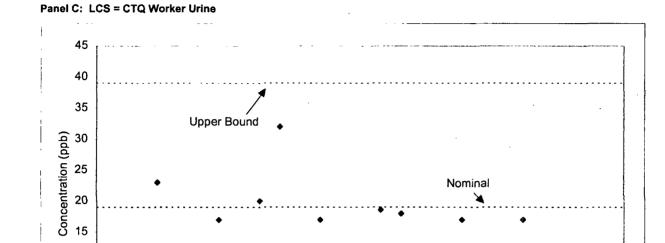


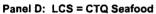
FIGURE 1. NMS RESULTS FOR URINARY ARSENIC LCS



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SDG

7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26



10

5

0

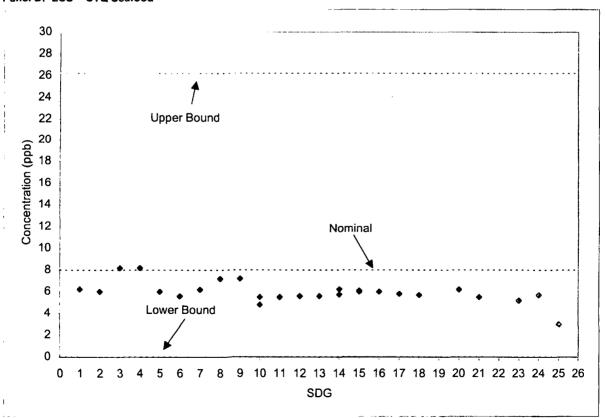
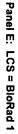
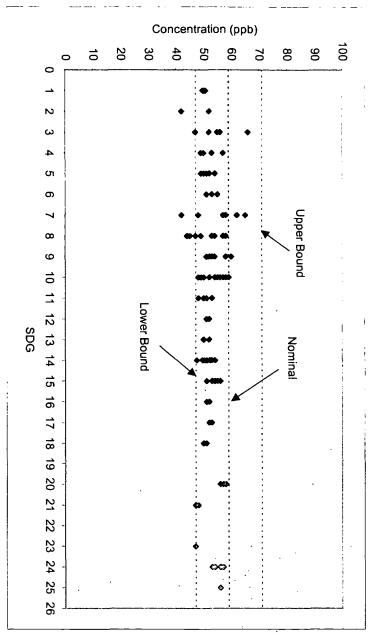
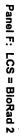


FIGURE 1. NMS RESULTS FOR URINARY ARSENIC LCS







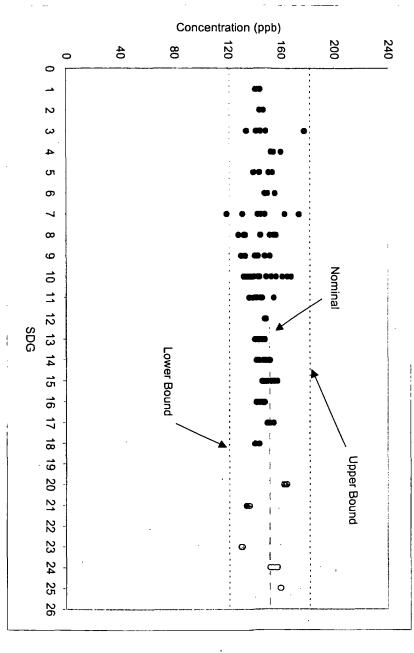


FIGURE 2 URINE-BASED (CASTEEL) PE SAMPLE RESULTS

Panel A: Blank (Unspiked) Urine

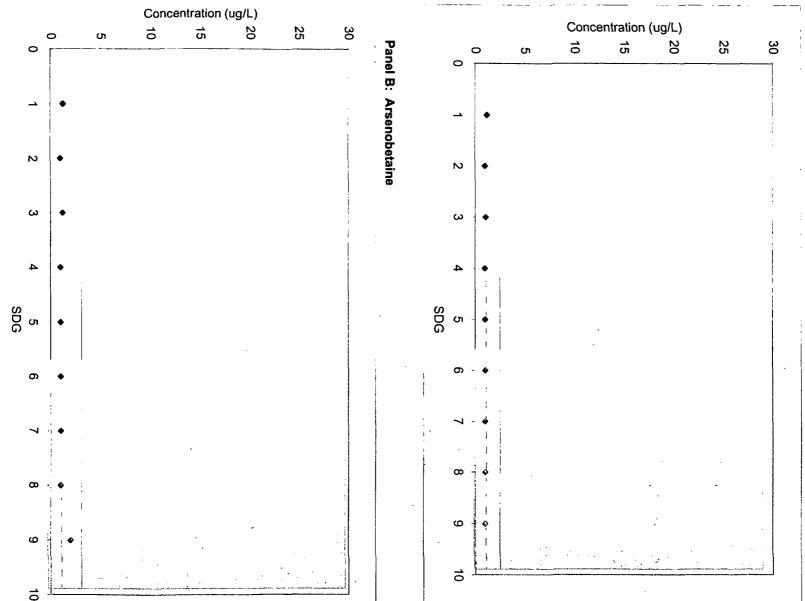
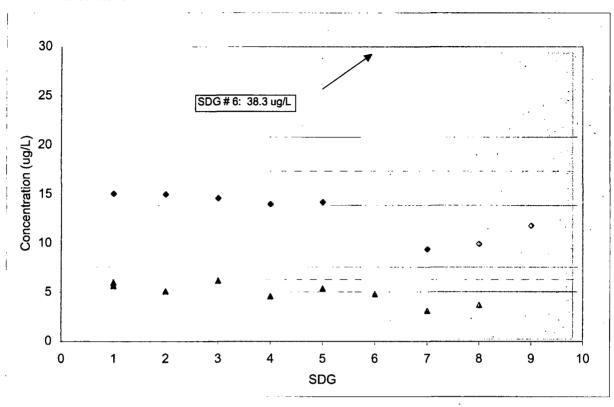


FIGURE 2 URINE-BASED (CASTEEL) PE SAMPLE RESULTS

Panel C: As+3



Panel D: As+5

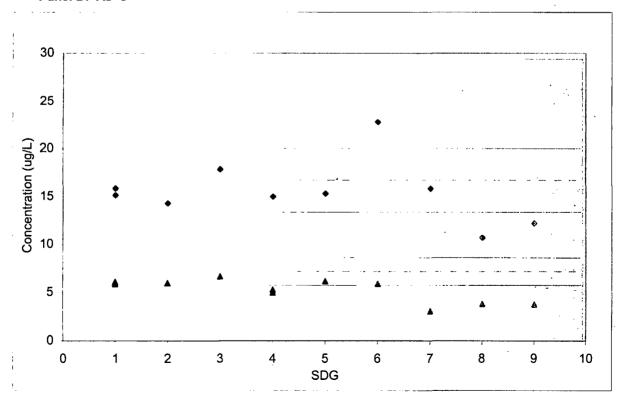


FIGURE 2 URINE-BASED (CASTEEL) PE SAMPLE RESULTS

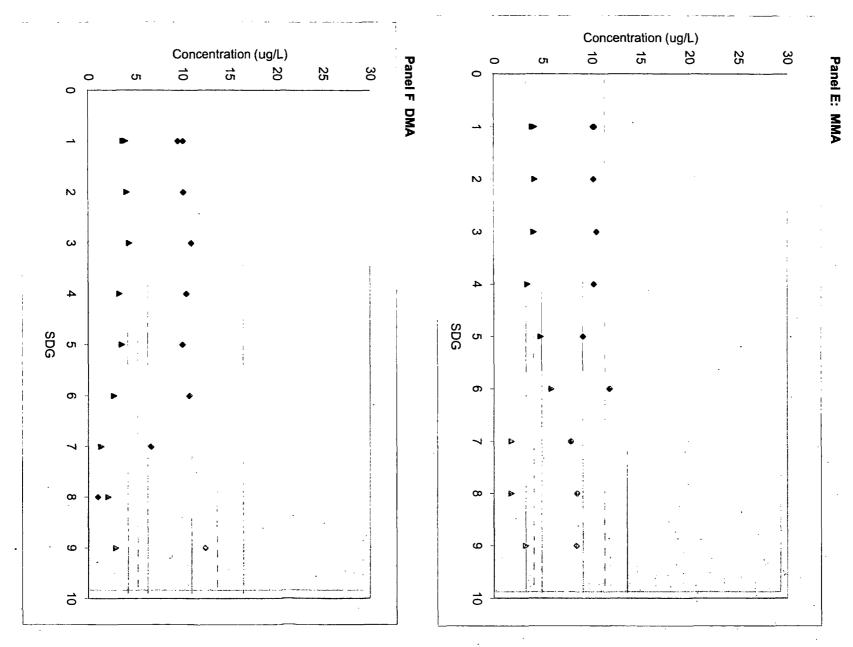
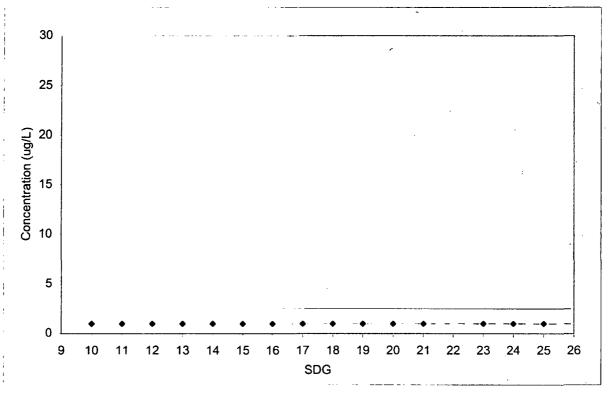


FIGURE 3 AQUEOUS-BASED (ERA) PE SAMPLE RESULTS

Panel A: Blank (Unspiked) Aqueous Solution



Panel B: Arsenobetaine

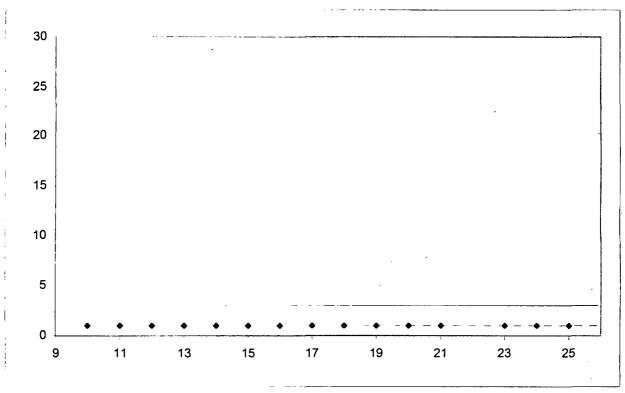
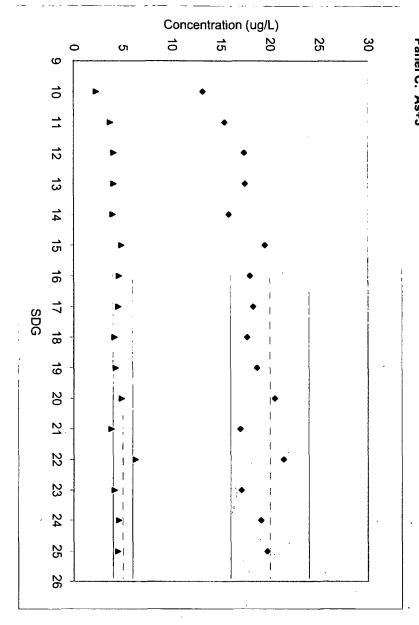


FIGURE 3 AQUEOUS-BASED (ERA) PE SAMPLE RESULTS

Panel C: As+3





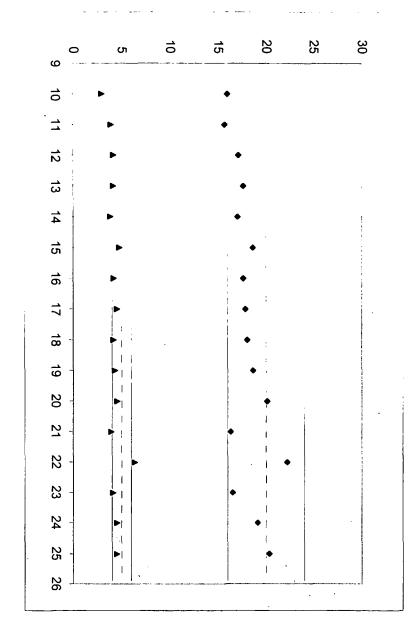


FIGURE 3 AQUEOUS-BASED (ERA) PE SAMPLE RESULTS



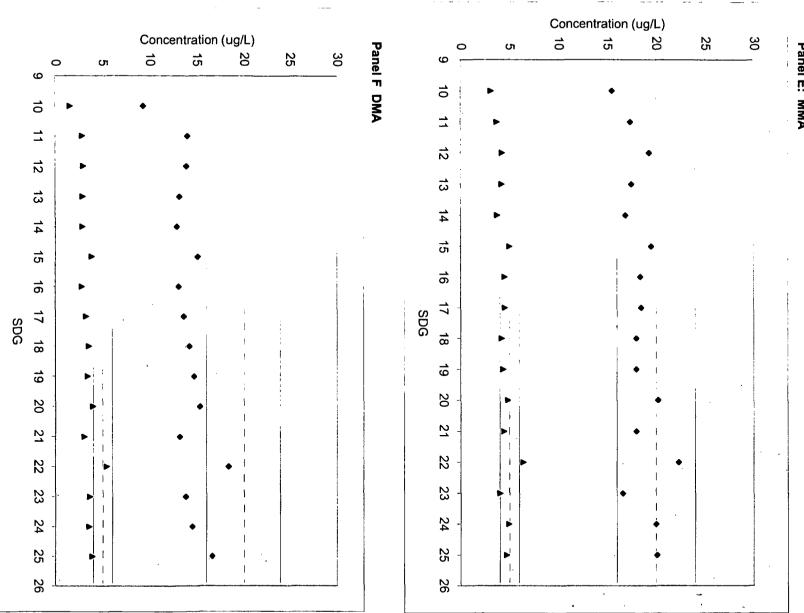


FIGURE 4 URINARY ARSENIC SPLIT SAMPLE COMPARISON

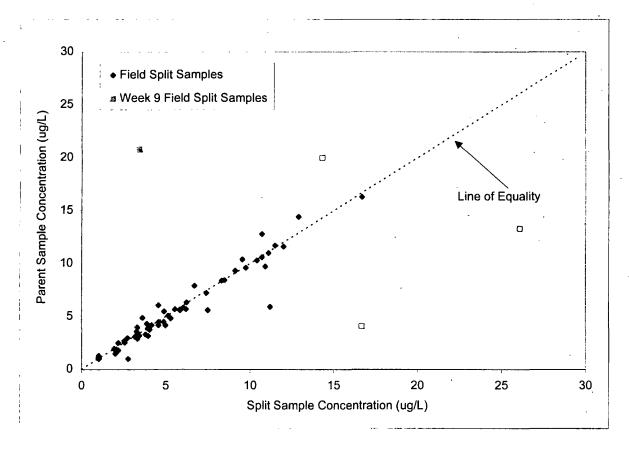
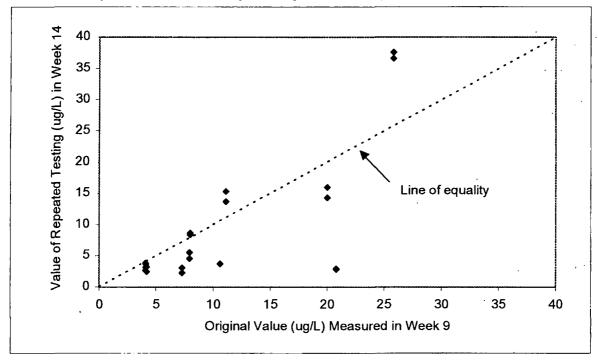


FIGURE 5. EVALUATION OF SAMPLES FROM SDG 9

Panel A: Comparison of Initial and Repeat Analyses of 11 samples from SDG 9



Panel B: Comparison of Splits from SDG 9 Measured in SDG 14

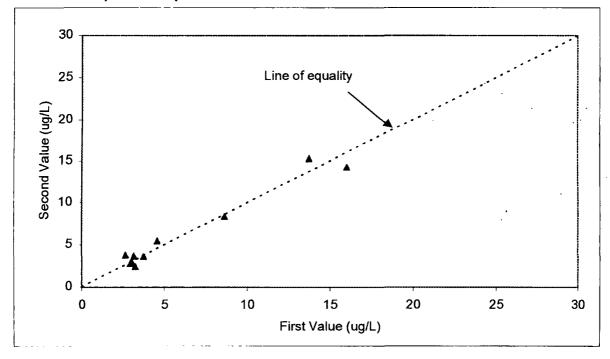


FIGURE 6. TAMARAC RESULTS FOR PbB LCS

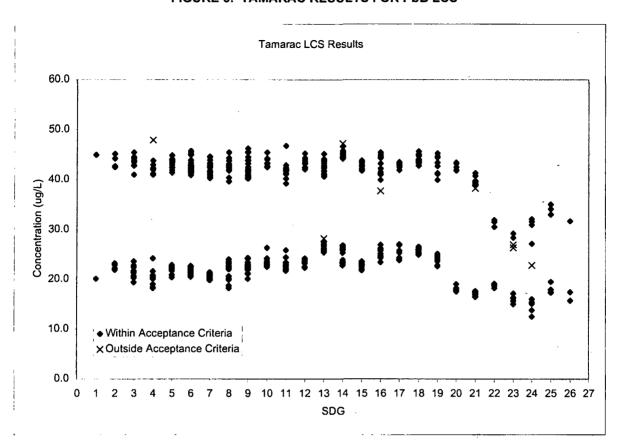


FIGURE 6. TAMARAC RESULTS FOR PbB LCS

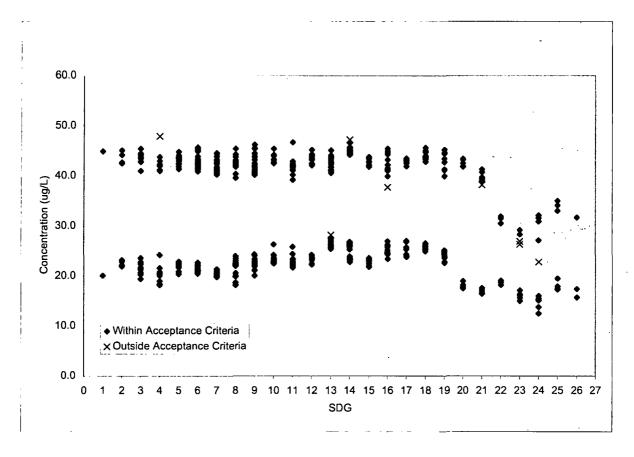
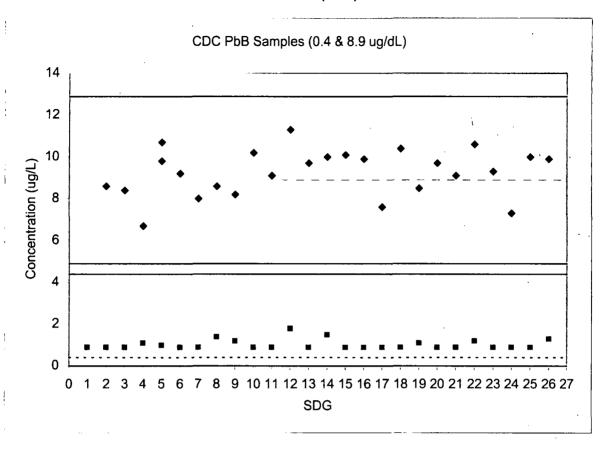


FIGURE 7. BLOOD LEAD (CDC) PE RESULTS



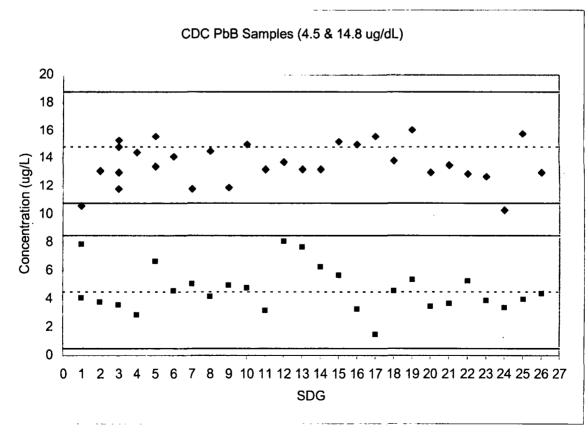


FIGURE 8. COMPARISON OF ORIGINAL AND DUPLICATE BLOOD LEAD RESULTS

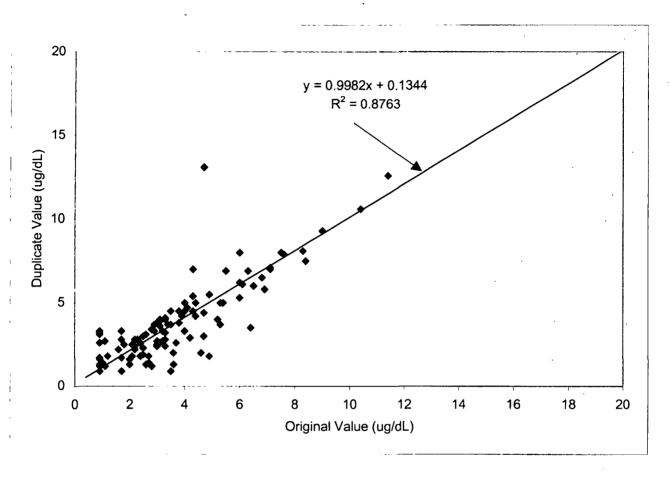
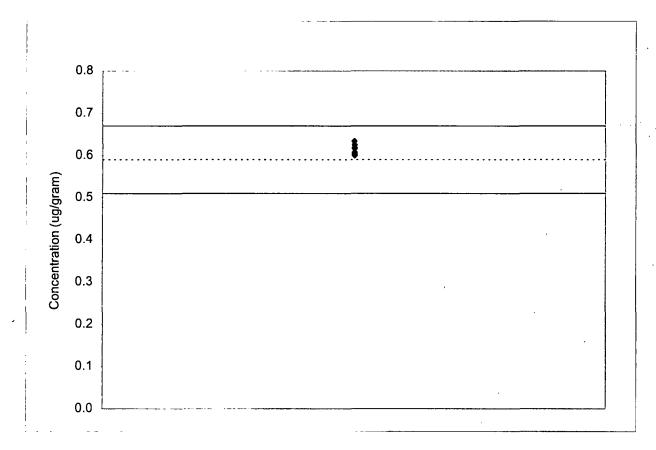


FIGURE 9. HAIR ARSENIC PE SAMPLES



APPENDIX A

FIELD AUDIT REPORTS



MEMORANDUM

To: Bonnie Lavelle

cc: Kristina Kaparich

From: John Guttmann

Date: July 1, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed the interviews on June 18, 2002 at the following residences:

Address	Activity
3621 Fillmore	Interview

The field team performed well throughout the interview process. Specifically, the field team performed well in addressing informed consent, confidentiality, and explaining the purpose of the study. Furthermore, the field team gathered all required information concerning child play activities/locations. However, the field team failed to survey any of the child play locations to estimate each location's % area of exposed soil.

Issues/Problems Observed

The field team failed to estimate % area of exposed soil at any of the child play locations.

Suggestions/Recommendations

Following an interview, sample teams must survey all locations described as a child play areas and estimate the % area of exposed soil.



MEMORANDUM

To: Bonnie Lavelle cc: Kristina Kaparich From: Jennifer Walter

Date: July 1, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC attempted to observe the collection of blood and urine samples on June 18, 2002 at the following residence:

Address	Activity
4901 Milwaukee	Blood and urine sample collection*

^{*}SRC attempted to observe sample collection activities at this residence, however the family was not home at the time of the appointment.

The residents were not available at the time of the appointment for sample collection and pickup. Thus, observations on sample collection and documentation procedures were not made. The sampling team left a "sorry we missed you note" and a message to re-schedule sample pickup and collection.

Sample team was approximately 10 to 15 minutes late for the scheduled appointment time.

Issues/Problems Observed

The sample team indicated that, in their experience, it was not uncommon for residents to miss their scheduled appointments.

Suggestions/Recommendations

SRC recommends calling residents ahead of time to confirm that they will be available for the interview and/or sample collection appointments, in order to better use time and human resources.



MEMORANDUM

To: Bonnie Lavelle cc: Kristina Kaparich From: Jennifer Walter

Date: July 1, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed the collection of blood and urine samples by two different field teams on June 28, 2002 at the following residences:

Address	Activity Observed
3324 Fillmore	Blood sample collection
3530 Adams	Blood and urine sample collection
3540 Adams	Blood and urine sample collection
3419 Fillmore	Blood and urine sample collection

The two field teams observed were very professional in their work and courteous to the families and children in each home visited.

The blood and urine samples were collected properly at all four residences, in accordance with the techniques specified in the project plans and during training. Additionally, sample numbers were assigned and documented correctly on the sample collection field sheets. Where samples were collected from multiple children at a residence, the field teams were thorough in verifying the name of the child being sampled (and also verifying spelling - as needed) to ensure that the sample number was assigned to the correct individual. In doing this, one team identified and corrected a potential mislabeling of a blood sample to the wrong individual.

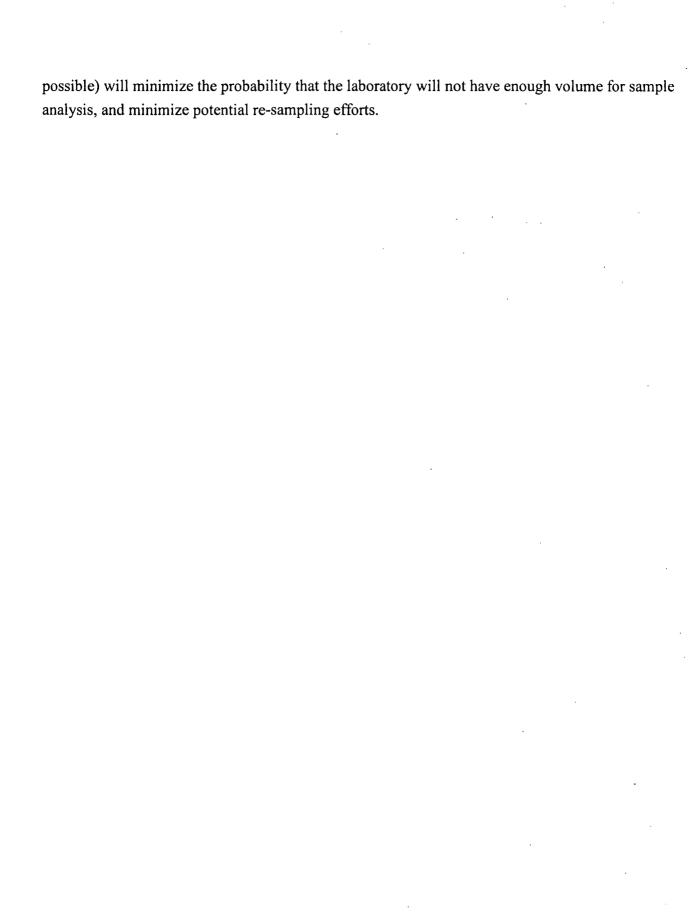
The blood samples collected at one residence (3540 Adams) were collected outdoors. Collecting samples indoors is probably preferred, in terms of ease on the field team being able to set up on a table surface and logistically not having to control for factors such as the wind that could potentially blow around sampling supplies and field sheets. However, if the family and/or child is more comfortable outdoors or requests that the sample be collected outdoors, as long as the field team can ensure that the sampling equipment and the child's finger are kept clean prior to and during sample collection, SRC does not foresee this as a problem. If a clean sampling environment cannot be guaranteed, (for example, the child goes to play in the dirt in between having his finger cleaned and having a blood sample collected), the sample should be collected indoors.

Issues/Problems Observed

No problems associated with sample collection and sample documentation were identified during the field audits.

Suggestions/Recommendations

During blood sample collection, SRC recommends that microtainers be filled as full of blood as possible from the initial finger prick. Although 50 uL is the minimum amount of blood required by the laboratory for analysis, sample collection is not required to end after this volume has been achieved, if the child is still bleeding and is not uncomfortable. Collecting more than the minimum 50 uL of blood (if





MEMORANDUM

To: Bonnie Lavelle cc: Kristina Kaparich From: Jennifer Walter

Date: July 2, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed the collection of blood and urine samples on July 2, 2002 at the following residences:

Address	Activity
3455 Adams	Blood and urine sample collection
3555 Cook	Blood and urine sample collection

The blood and urine samples were collected properly at both residences, in accordance with the techniques specified in the project plans and during training. Additionally, sample numbers were assigned and documented correctly on the sample collection field sheets.

Issues/Problems Observed

No problems associated with sample collection and sample documentation were identified during the field audits.

Suggestions/Recommendations

None.



MEMORANDUM

To: Bonnie Lavelle

cc: Kristina Kaparich

From: Jennifer Walter Date: July 22, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed the collection of blood and urine samples on July 17, 2002 at the following residences:

Address	Activity
7958 Clayton	Interview, Sample collection (blood and urine)
4456 Clayton	Interview*
3716 Fillmore	Interview*

^{*}SRC attempted to observe interview activities at this residence, however the family was not home at the time of the appointment.

The field team clearly and effectively explained the purpose of the study, the consent form and administered the surveys. The team was very accommodating in scheduling additional sample pickup/collection times for children who were not present and in suggesting/providing another pediatric bag for an additional attempt to collect a urine sample from an infant in the household.

The field team had developed a self-QA system by having team members check each other's work as the data were collected at a residence by reviewing the consent, census, interview, and soil exposure surveys, and the sample collection data sheets. When only one individual was assigned to a residence, the individual commented that he would review his own work after completing the sample documentation and/or survey forms.

The blood and urine samples were collected correctly, using the techniques specified in the project plans and during training. Additionally, sample numbers were assigned and documented correctly on the sample collection field sheets.

The consent, child census, soil exposure survey and the signs and symptoms survey were completed consistent with project plans and training.

Issues/Problems Observed

No problems associated with sample collection, sample documentation or interviewing were identified during the field audits.

Parental consent for collection of urine samples at 4958 Clayton was obtained at the time of urine sample pick up. However, information on the initial visit to this residence was not available to know if the parent's consent had already been obtained for urine sample collection.

Suggestions/Recommendations

Parent consent on sample collection should be obtained prior to sample pickup/collection.



MEMORANDUM

To: Bonnie Lavelle cc: Kristina Kaparich From: Jennifer Walter

Date: August 20, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed an interview and the collection of blood samples on August 20, 2002 at the following residences:

also 9/5/02 attempted interview audit at 3306 Gilpin St. - family home, wanted to reschedule

Address	Activity
4758 Williams	Interview*
4607 Franklin	Interview, Sample collection (blood)*

^{*}SRC attempted to observe interview activities at this residence, however the family was not home at the time of the appointment.

The residents at 3748 Williams Street were not available at the appointment time for the interview. The field team left a "sorry we missed you" notice.

The field team clearly explained the purpose of the study, the consent form and administered the soil child census, exposure surveys, and the signs and symptoms survey and were very courteous and professional.

The blood samples were collected correctly, using the techniques specified in the project plans and during training. The field team did an excellent job collecting adequate sample volumes from the 2 children, especially from one child who started crying during sample collection.

Full sample documentation was not observed, as the field team did not have the blood sample tracking form or blood sample sheets with them as part of their field supplies. Temporary labels (names) were assigned to the blood samples as they were collected, which were to be replaced with blood field sample IDs immediately following the interview at the field office.

The consent, child census, soil exposure survey and the signs and symptoms survey were completed consistent with project plans and training.

Issues/Problems Observed

The field team was missing their field data sheet/sample labeling supplies. No other problems associated with sample collection were identified during the field audit.

Suggestions/Recommendations

Develop a checklist of all supplies/materials needed for a sample collection and interview visits and review the list before going to an appointment.



MEMORANDUM

To:

Bonnie Lavelle

cc:

Kristina Kaparich

From: Jennifer Walter

Date: August 9, 2002

RE:

QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the sample preparation activities conducted by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed the preparation of urine samples (both field and PE samples) for analysis and PE (field split and PE standards) sample log documentation on August 5, 2002 at the University of Colorado Health Sciences Center.

Two UCHSC staff prepared the field and PE urine samples for shipment. The samples for this shipment were prepared in the following order: field samples, field splits, and lastly urine PE samples.

Field Samples .

Field samples were prepared in accordance with project plans by transferring 3-4 mL of the parent urine sample into a 15 mL tube. The 15 mL tube and parent sample collection container were both pre-labeled with sample IDs in the field by the sampling teams and stored together in a ziploc bag. Before preparing the samples, the UCHSC staff verified that the sample numbers on the 15 mL tube matched the sample number on the parent container that were paired together in the ziploc bag. A new disposable pipette tip was used for each sample. Gloves were changed periodically, as needed (i.e., after handling a parent sample container where urine had leaked and gloves had become dirty).

Field Splits

Split samples were prepared in accordance with project plans and labeled correctly by the UCHSC staff. Field splits were prepared at a frequency of 5%; four field splits were sent for 75 field samples for a rate of 5.3%. The split samples were randomly inserted into the sample chain by selecting sample labels from the list of pre-printed urine sample IDs that were not consecutive in sequence to each other or with the sample ID of the associated parent sample. One UCHSC staff member prepared the split samples and dictated the parent sample number information to the other staff member to record in the QA/QC log.

PE samples

PE samples were prepared in accordance with project plans and labeled correctly. One of each of the ten PE standards were prepared by the UCHSC staff to be submitted with the field samples. The 15 mL sample tubes for the PE samples were pre-labeled with sample IDs that had been removed randomly from urine sample sheets before the sample sheets were distributed to the field teams to ensure randomness in the sampling chain. Sample IDs had also been pre-affixed to a blank QA/QC log page. One UCHSC staff prepared the PE samples and dictated the PE sample type information (i.e, As+3, 15 ug/L) to the other staff member to record in the QA/QC log.

Preparation of field split and PE samples separately, and by one staff member appeared to minimize the chance of mixing up or mislabeling field split samples and PE standard samples.

Issues/Problems Observed

During PE sample preparation, mold was observed growing in 4 of the 10 PE standard types: As+5_15 ug/L; As+5_5ug/L, MMA 5 ug/L, and As+3_5 ug/L. The PE standards with mold were not used for PE sample preparation. Additional bottles of the same PE standard type that did not appear to be impacted with mold were used to prepare the PE standards sent with this shipment.

Suggestions/Recommendations

Urine PE standard samples that contain mold should not be used in preparing future PE samples.



MEMORANDUM

To: Bonnie Lavelle cc: Kristina Kaparich From: Jennifer Walter

Date: August 9, 2002

RE: QA Field Audits

In accordance with the Quality Assurance Plan for the UCHSC Study for Soil Arsenic and Lead Exposure at VBI70, SRC has conducted an audit of the field data and sample collection procedures by UCHSC staff. This memo summarizes SRC's observations during the field audit, identifies any issues or problems, and presents any recommendations and suggestions for improving field interview and sampling activities.

Description of Activities Observed

SRC observed an interview and the collection of blood samples on August 9, 2002 at the following residence:

Address	Activity
4315-B Josephine	Interview, Sample collection (blood)

The field team clearly explained the purpose of the study, the consent form and administered the soil child census, exposure surveys, and the signs and symptoms survey and were very courteous and professional.

The blood samples were collected correctly, using the techniques specified in the project plans and during training. The field team did an excellent job collecting adequate sample volumes from the 2 children, especially from one child who started crying during sample collection.

Full sample documentation was not observed, as the field team did not have the blood sample tracking form or blood sample sheets with them as part of their field supplies. Temporary labels (names) were assigned to the blood samples as they were collected, which were to be replaced with blood field sample IDs immediately following the interview at the field office.

The consent, child census, soil exposure survey and the signs and symptoms survey were completed consistent with project plans and training.

Issues/Problems Observed

The field team was missing their field data sheet/sample labeling supplies. No other problems associated with sample collection were identified during the field audit.

Suggestions/Recommendations

Develop a checklist of all supplies/materials needed for a sample collection and interview visits and review the list before going to an appointment.